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Virginia Board of Pharmacy

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First Publication of Electronic Newsletter

The Virginia Board of Pharmacy is now contracting with the National Association of Boards of Pharmacy® to publish a quarterly electronic newsletter. This four page publication will consist of both state and federal news, and will be posted on our Web site. Alerts of newly published e-newsletters along with a link will be sent via e-mail to all pharmacists and pharmacy technicians who have provided a current e-mail address to the Board. Please note that the Board cannot use the mandated e-mail address within the Emergency Contact Information field. Only the e-mail address volunteered in the Personal Information field will be used. Therefore, please be sure to maintain your current e-mail address in this field if you want information e-mailed to you. You may do this online through the Board's Web site or you may write or e-mail the Board providing the updated information. The Board will strive to provide current and useful information. If you have any suggestions for future topics, please contact us at pharmbd@dhp.virginia.gov or 804/662-9911.

Recent Regulatory Actions

For the latest revision of Board Regulations, dated January 11, 2006 click on www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm#reg.

Schedule VI Prescriptions

Effective January 11, 2006, a prescription for a Schedule VI drug or device is valid for one year from the date of issuance unless the prescriber specifically indicates for a longer period of time, not to exceed two years. Prescriptions written prior to this date may be dispensed for up to two years from the date of issuance as stated in the previous regulation, or for no longer than indicated by the prescriber. As originally drafted, the amendment to 18 Virginia Administrative Code (VAC) 110-20-320, would have limited a Schedule VI prescription to one year. However, a compromise with the Board of Medicine created a default of one year with a provision to allow prescribers to specifically authorize refills for a maximum of two years.

The Board recently addressed concerns with this regulatory change at the March 2006 Board meeting and the following is offered as guidance:

- "prn" refills are valid for one year from the date of issuance;
- "99" refills are valid for two years from the date of issuance (frequently used to indicate refills for oxygen prescriptions);
- A 30-day supply with 12 refills indicates that a 30-day supply shall not be dispensed more than 13 times within two years from the date of issuance; and
- A 30-day supply with 11 refills indicates that a 30-day supply shall not be dispensed more than 12 times within one year from the date of issuance.

As always, the prescriber should be contacted if clarification is needed.

Prescription Blank Requirements

In 2003, the General Assembly eliminated the Virginia Voluntary Formulary as the standard for generic substitution and put into place Food and Drug Administration's "Orange Book" as the new standard. For this reason, the prescription blank requirement for a check box stating "Voluntary Formulary Permitted" was removed from law, and there is now no required format for a written prescription blank. Because the term "brand medically necessary" is a nationally accepted term and one that is required by Medicaid in order to ensure payment for a branded product, this phrase was adopted in Virginia law as the required term to prohibit generic substitution. The new law gave prescribers three years to deplete their stock of the "old" prescription blanks before the new requirement takes effect in 2006. Thus, after July 1, 2006, checking the old "dispense as written" box will not prohibit generic substitution. Physicians must indicate "brand medically necessary" on the prescription to prohibit such substitution. Pharmacists may continue to accept prescriptions with the two check box format until the physician exhausts his supply, but the two boxes will have no value. The law does not specify how the phrase "brand medically necessary" must be indicated on the blank. It can be written on the prescription by the prescriber or by an agent, it can be stamped on the prescription, indicated by a checked box, etc.

For more information on prescription blank requirements, click on www.dhp.virginia.gov/pharmacy/pharmacy_faq.htm#PresBlank.

Prescription Monitoring Program Update

Letters and manuals were sent out the week of March 20, 2006, alerting dispensers of the statewide expansion of the prescription monitoring program. Pharmacies in southwest Virginia will begin reporting prescriptions dispensed in Schedules II, III, and IV in May 2006. The report, which is due no later than May 25, 2006, encompasses data from May 1 through May 15, 2006. Dispensers in the rest of the Commonwealth and nonresident pharmacies will begin reporting in June 2006 with data from June 1 through June 15, due no later than June 25, 2006. For questions regarding the data collection process, please contact the new contractor, Optimum Technology, Inc, at 866/683-2476 or via e-mail at varxreport@otech.com.

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben®, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien®, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis. An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a $175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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There are various methods for reporting prescription data; the easiest and fastest way to report is through an Internet-based system via secure upload procedures. This method also provides the dispenser with feedback on file acceptance or rejection in a much shorter timeframe. In most cases, entire files will not be rejected, just the individual records that do not meet criteria within a file. Other methods for reporting will include secure file transfer protocol; diskette (includes CD, DVD, 3 ½ inch diskette); and online access for submitting zero reports and universal claim forms.

Pharmacists May Now Make Requests

Pharmacists may query the Prescription Monitoring Program to assist in verifying the validity of a prescription in compliance with 18 VAC 76-20-70 for posting notice. To ensure compliance, a pharmacy may post a sign in public viewing distance disclosing the fact that the pharmacist may access information contained in the program files on all Schedule II, III, and IV prescriptions dispensed to a patient. Requests to the program can currently be made via fax or mail. Technology for online requests is expected to be available in May 2006. Online reports will be received in a secured Web page.

Information will be posted on the Prescription Monitoring Program Web site (www.dhp.virginia.gov, found under Services for Practitioners) as it becomes available. For questions, please e-mail pmp@dhp.virginia.gov or call 804/662-9129. The program fax number is 804/662-9240.

Web Site Topics, Guidance Documents, and Inspection Violations

While online, take the time to explore the extensive information available on the Board's Web site. Popular points of interest include: the most current laws and regulations; Board applications; access to update personal information such as address changes or e-mail address changes; Board *Newsletters*; and frequently asked questions (FAQs). Additionally, Board interpretation of many laws and regulations can be found online under Guidance Documents as well as a listing of the most frequently-cited Inspection Deficiencies, known as the "Dirty Dozen."

Guidance Documents

A recently revised Guidance Document, No 110-7 entitled "Practitioner/Patient Relationship and the Prescribing of Drugs for Family or Self" resulted from recent regulations promulgated by the Board of Medicine. This helpful document explains which prescribers may write prescriptions for their family or self and what requirements must be in place for compliance. Other useful guidance documents include: 110-8, which explains the prescriptive authority of the various prescribers to include nurse practitioners, physician assistants, and TPA-certified (Therapeutic Pharmaceutical Agent) optometrists; 110-27, which identifies the responsibilities of a pharmacist-in-charge (PIC); and 110-35, which summarizes the necessary elements for a valid prescription that is either written, transmitted orally, faxed, or electronically transmitted. A complete listing of all guidance documents can be found at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

Inspection Deficiencies

For a listing of the most frequently cited pharmacy inspection deficiencies, click on www.dhp.virginia.gov/Enforcement/guidelines/76-20.1.pdf. Pay special attention to number nine on the Community Pharmacies 2005 list regarding pharmacy technicians. Deficiencies related to these individuals appear to be on the rise. Please note that technicians must be registered with the Board, and that the PIC is ultimately responsible for ensuring this. Technicians can become registered via two ways as explained in an FAQ found at www.dhp.virginia.gov/pharmacy/pharmacy_faq.htm#TechRegistration. If a technician plans to register via a Board-approved training program, and is working as a technician while in training, then the PIC should have on-site documentation that the technician is currently enrolled in a program and the date the technician began the program. Remember this type of technician cannot perform technician duties longer than nine months without becoming Board registered. Pharmacy Technician Certification Board certified technicians must become Board registered before performing any technician duties in a pharmacy. Additional training for all pharmacy technicians includes a site-specific training program. This program should be consistent with the practices specific to the individual pharmacy, such as training in the specific pharmacy software used, or compounding if a compounding pharmacy. Every pharmacy must have documentation on site of successful completion of this program for each pharmacy technician. Please refer to 18 VAC 110-20-111 for retention information of these documents.

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